PROVIDER BULLETIN

THIS ISSUE

Autologous Chondrocyte Implantation

TO:
Ambulatory Surgery Centers
Physicians
Physician Assistants
Hospitals
Clinics

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Purpose

The purpose of this bulletin is to update the department's coverage policy for Autologous Chondrocyte Implantation (ACI). The coverage criteria are updated: **ACI is covered for cartilaginous defects femoral condyle (medial, lateral <u>or trochlear</u>).** Specific coverage criteria are provided in this bulletin.

The Provider Bulletin is effective immediately for State Fund and Self-Insurance claims in all locations and replaces ACI coverage criteria in Provider Bulletin 03-02.

What is Autologous Chondrocyte Implantation?

Autologous chondrocyte implantation (ACI) may be used to treat patients with cartilaginous defects of the femoral condyle. The ACI process involves:

- Obtaining healthy chondrocyte cells from a patient's knee.
- Culturing the cells through a process termed Carticel.
- Implanting the cultured chondrocytes back into the patient using a surgical procedure.

Surgeon Experience with ACI Is Required

The insurer will reimburse physicians who have completed Genzyme Tissue Repair's training course on ACI. In addition, physicians must:

A. Have performed or assisted on 5 or more ACI procedures.
            OR
B. Perform ACI under the direct supervision and control of a surgeon who has performed 5 or more ACI procedures.

Only physicians who meet these requirements should request payment authorization for ACI. Payment authorization for ACI is premised upon the insurer's understanding that only surgeons meeting the stated criteria will perform the procedure.

When is ACI a covered procedure?

ACI is a covered procedure in patients who meet ALL of the following criteria.

A. An acute, work-related trauma to the knee caused the cartilaginous lesion. For example, the full-thickness cartilage loss results from a shearing injury or a direct blow.

AND

B. Evidence shows a single, clinically significant, symptomatic lesion. The lesion is:
   i.   Located on a load-bearing surface of the medial or lateral femoral condyle or it is located in the trochlea,
            and
   ii.   Full-thickness (Modified Outerbridge Grade III-IV[1]) involving only cartilage,
            and
   iii.   Measures between 1 to 10 cm^2 in area.

AND

C. Evidence shows that the knee is stable and has:
   i.   Intact, fully functional menisci and ligaments,
            and
   ii.   Normal alignment,
            and
   iii.   Normal joint space.

AND

D. The patient attempted and failed BOTH of the following treatments for the lesion:
   i.   Appropriate non-surgical treatment (e.g., minimum 2 months of physical therapy),
            and
   ii.   Traditional surgical intervention (i.e., microfracture, drilling, abrasion, osteochondral graft). Debridement alone does not constitute a traditional surgical intervention for these purposes.

AND

E. The patient has the following characteristics:
   i.   Less than 60 years old,
            and
   ii.   Body Mass Index < 35,[2]
            and
   iii.   Is capable and willing to follow the rehabilitation protocol.

When is ACI not a covered procedure?

ACI is not a covered procedure in any of the following circumstances.

A. The lesion that requires treatment:
   i.   Involves any portion of the patellofemoral articular cartilage,
            or
   ii.   Involves bone,
            or
   iii.   Is due to osteochondritis dissecans.

OR

B. A "kissing lesion" of Modified Outerbridge Grade II, III, or IV exists on the opposing tibial surface.

OR

C. The patient has an arthritic condition that appears on standing X-rays as joint space narrowing, osteophytes, or changes in the underlying bone. The insurer will exclude a patient if the inflammatory (rheumatoid or other) or degenerative (osteoarthritis) arthritis is any of the following.

> i. Mild and diffuse,
>> or
> ii. Moderate to severe and localized,
>> or
> iii. Moderate to severe and diffuse.

OR

D. The patient has an unhealthy cartilage border. The synovial membrane in the joint may be used as a substitute border for up to ¼ of the total circumference.

OR

E. The patient has undergone a total meniscectomy of either compartment in the affected knee. The compartment in which the patient will receive ACI must contain at least 1/3 of the posterior meniscal rim.

OR

F. The patient has a history of anaphylaxis to Gentamicin or sensitivity to materials of bovine origin.

OR

G. Chondrocalcinosis is diagnosed during the cell culturing process.

What documentation does the physician submit?

Documentation needs to address all of the coverage criteria for ACI. The insurer may require Physicians to submit the following documents to the utilization review (UR) vendor to define the patient's knee condition.

A. Operative notes.
B. Reports of standing X-rays.
C. Arthroscopy results.

Does payment for ACI require prior authorization?

Yes, the insurer requires prior authorization for payment of each stage of ACI. Physicians must first request payment for an initial arthroscopy and then request payment for ACI.

How does a provider request a review for ACI?

To initiate reviews for a <u>self-insured</u> claim, contact the self insurer.

To initiate the reviews for a <u>State Fund</u> claim, physicians submit their requests to the Department's utilization review (UR) contractor, Qualis Health. UR makes a recommendation to the claim manager to authorize or to deny the request for payment. The claim manager makes the final determination. The procedure for requesting payment and performing ACI for a State Fund candidate follows:

Physician	1. Submits a request for an arthroscopy to UR vendor, including the codes for cell culture and implantation
UR vendor	2. Reviews case 3. Sends recommendation to claim manager
Claim Manager	4. Authorizes payment for arthroscopy 5. Notifies physician of decision
Physician	6. Performs an arthroscopy and harvests cells 7. Sends cells to US Bioservices 8. Asks US Bioservices to hold cells 9. Assesses patient's candidacy based on criteria 10. Submits request for ACI to UR vendor 11. Awaits authorization of payment from the claim manager
UR vendor	12a. Reviews case 12b. Sends recommendation to Claim Manager
US Bioservices	12c. Holds cells 12d. Awaits notification from physician
Claim Manager	13. Authorizes payment for the cell culture 14. Authorizes payment for the implantation procedure 15. Notifies physician of decision
Physician	16. Authorizes US Bioservices to culture cells after receiving payment approval from claim manager 17. Schedules implantation procedure
US Bioservices	18. Cultures cells 19. Sends cultured cells to operating room 20. Bills the insurer for culturing the cells
Physician	21. Receives cells 22. Performs implantation procedure

What are the billing codes for ACI?

Procedure	CPT Code	Billed By
Initial Arthroscopy and Cell Harvest	29870	Physician
Implantation	27412	Physician
Procedure	HCPCS Code	Billed by
Cell Culture	J7330	US Bioservices

Where is more information available?

Contact Josh Morse at mojo235@lni.wa.gov or (360) 902-5026 for more information about ACI. Additional information is available online at:
http://www.lni.wa.gov/ClaimsIns/Providers/Treatment/SpecCovDec/default.asp